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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,474	11/28/2003	Jaeon Jung	13010-02USA	1022
35736	7590	02/08/2005	EXAMINER	
JHK LAW P.O. BOX 1078 LA CANADA, CA 91012-1078			FOREMAN, JONATHAN M	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/724,474

Applicant(s)

JUNG ET AL.

Examiner

Jonathan ML Foreman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-13 and 15-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-13 and 15-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 5 – 9, 12, 13 and 19 - 21 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,353,868 to Joslin et al.
3. In regards to claims 1, 2, 5 – 9 and 12, Joslin et al. discloses a device for collecting biological samples comprising nucleic acid including at least one collection protrusion comprising a tip (28), at least one pad (60) for contacting the tip (Col. 4, lines 54 - 55), where the pad comprises chemical preservatives or enzyme inhibitors (Col. 3, lines 55 - 59), and at least one cap (14). The tip is a wick, spoon, pick or swab (Col. 2, line 10). Joslin et al. discloses the cap (14) being connected to the device (Col. 3, line 55) and detached from the device (Col. 2, line 41). The cap slidably encloses the device (Col. 2, lines 34 – 36). The device comprises plastic (Col. 4, lines 34 - 37).
4. In regards to claims 13 and 19 – 21, Joslin et al. discloses at least one removable collection protrusion (18) comprising at least one tip (28), at least one pad (60) for contacting the tip, and a storage area for collecting a solid sample (Col. 1, lines 11 – 14). The solid sample collection area comprises a lid (14).
5. Claims 1, 2, 5, 8 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,980,828 to McClintock et al.

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In regards to claims 1, 2, 5, 8 and 9, McClintock et al. discloses a device for collecting biological samples comprising nucleic acid including at least one collection protrusion comprising a tip (42), at least one pad (Col. 7, lines 26 – 30) for contacting the tip (Col. 8, lines 28 – 31), where the pad comprises chemical preservatives or enzyme inhibitors (Col. 8, lines 2 – 10), and at least one cap (Col. 8, lines 31 – 33). The tip is a wick, spoon, pick or swab (Col. 7, lines 54 – 60). McClintock et al. discloses the cap being connected to the device (Col. 8, lines 31 – 33). The device comprises plastic (Col. 7, lines 7 – 10).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 13 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,883,068 to Dechow in view of U.S. Patent No. 5,275,953 to Bull.

In regards to claims 13 and 17, Dechow discloses a device for collecting samples including at least one collection protrusion (16) comprising at least one tip (16a); at least one pad (18; Col. 2, line 52) for contacting the tip; and a storage area (17). The storage area is fitted with tubing (16). However, Dechow fails to disclose the storage area being coated with a chemical preservative or enzyme inhibitor. Bull discloses a device for collecting samples wherein the storage area is coated with a chemical preservative or enzyme inhibitor (Col. 3, lines 22 – 31). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the storage area as disclosed by Dechow to include a coating of a chemical preservative or enzyme inhibitor as taught

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by Bull in order to maintain a blood specimen in vitro in essentially the same state as found in vivo (Col. 2, lines 60 – 63).

8. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,883,068 to Dechow in view of U.S. Patent No. 5,275,953 to Bull as applied to claim 13 above, and further in view of U.S. Patent No. 4,370,987 to Bazell et al.

In regards to claims 15 and 16, Dechow in view of Bull discloses a device for collecting samples including a storage area comprising a pre-evacuated chamber (17; Col. 2, lines 53 – 55). However, Dechow in view of Bull fails to disclose the storage area being fitted with a syringe having unidirectional piston. Bazell et al. discloses a device for collecting samples including as a storage area a syringe having unidirectional piston (Col. 3 lines 55 – 59). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pre-evacuated storage area as disclosed by Dechow in view of Bull to include a syringe having a unidirectional piston as taught by Bazell et al. in order to adjust the vacuum in the storage area for collecting different amounts of sample (Col. 1, lines 33 – 36).

9. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,883,068 to Dechow in view of U.S. Patent No. 5,275,953 to Bull as applied to claim 17 above, and further U.S. Patent No. 6,602,205 to Erickson et al.

In regards to claim 18, Dechow in view of Bull discloses a device for collecting samples including a tubing (16), but fails to disclose the tubing being capillary tubing. Erikson et al. teaches a device for collecting samples having a capillary tubing (12). It would have been obvious to one having ordinary skill in the art to modify the tubing as disclosed by Dechow in view of Bull to be a capillary tubing as taught by Erikson et al. in order collect the sample with minimal pain (Col. 5, lines 50 – 53).

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10. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,353,868 to Joslin et al. in view of U.S. Patent Application Publication No. 2002/0161313 to Sak.

In regards to claims 10 and 11, Joslin et al. discloses a device for collecting biological samples, but fails to disclose written instructions on using device. However, Sak discloses a device for collecting biological samples and teaches instructions on using the device [0038]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include written instructions as taught by Sak with the device as disclosed by Joslin et al. in order to provide the user with a reference for using the device.

### *Response to Arguments*

11. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

### *Conclusion*

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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